(Amended) 15. A chemical composition used to stimulate weight loss in a patient, comprising:

acarbose; and

a sustained release matrix,

wherein said acarbose and sustained release matrix are combined to form a mixture.

Please add new claim 43 as follows:

(New) 43. A method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.

REMARKS

Applicant wishes to thank the Examiner for the consideration given this case to date. Applicant has had an opportunity to carefully consider the Examiner's action, and respectfully submits that the application, as amended, is now in condition for allowance.

As examined, claims 1-42 were pending.

THE EXAMINER'S ACTION

In the Office Action dated July 9, 2002, the Examiner:

rejected claims 1-14 under 35 U.S.C. § 102(e) as being anticipated by Patel et al., U.S. Patent No. 6,309,663 (hereafter "the '663 reference");

rejected claims 15-27 under 35 U.S.C. § 102(e) as being anticipated by Patel et al., the '663 reference;

rejected claims 28-41 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., U.S. Patent No. 5,643,874 (hereafter "the '874 reference");

rejected claims 15-27 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., the '874 reference; and

rejected claims 28-42 under 35 U.S.C. § 103(a) as being unpatentable over Bremer et al., (the '874 reference) in view of Patel et al. (the '663 reference).

REJECTIONS UNDER 35 U.S.C. § 102(e)

In his rejection of claims 1-14, Examiner cites to the '663 reference and states that "The Patel patent discloses that the dosage form can be designed for extended release, which can be effected by a coated matrix composition." (see Office Action, p.2). Furthermore, the Examiner has taken the position that the '663 reference "comprises mixing acarbose and a coating." (Office Action, p.3).

Applicant's amended Claim 1 calls for, among other things, mixing acarbose with a sustained release matrix to form a mixture. The '663 reference does not teach that which is encompassed by claims 1-14 because the '663 reference does not disclose the combination of acarbose and a sustained release matrix into a mixture Rather, the '663 reference discloses the coating of acarbose by a sustained release matrix.

Applicant's claims are not anticipated by the '663 reference because, as indicated in Applicant's specification and claims, Applicant's invention includes the combination of acarbose and a sustained release matrix, not merely the placement of a coating on an acarbose composition. It is the novel composition comprising a combination of acarbose and a sustained release matrix, not just a coating placed over an acarbose formulation, that makes Applicant's invention patentable over the '663 reference. Therefore, because independent claim 1 is not anticipated by the '663 reference, all claims dependent therefrom are also not anticipated.

The Examiner, in his rejection of claims 15-27, has stated that the '663 reference discloses a composition comprising surfactants and a hydrophilic therapeutic agent, such as acarbose (see Office Action, p. 3). Further, the Examiner cites to Column 38, 2nd Paragraph of the '663 reference, which describes that the composition may be coated with a matrix composition in order to effectuate extended release of the composition. The '663 reference states that the dosage form of the composition can be designed for extended release via a coating composition (see Column 38, 2nd paragraph).

Applicant's amended Claim 15 claims a composition including acarbose and a sustained release matrix, where the acarbose and sustained release matrix form a mixture. In Applicant's dependent claims, the acarbose-sustained release matrix mixture may further be coated with a sustained release matrix. It is clear from Applicant's specification that the acarbose and sustained release matrix are combined to form an acarbose-sustained release matrix mixture, not merely that the acarbose is coated with a sustained release matrix. Though Applicant's composition comprising acarbose and a sustained release matrix may, in an alternative embodiment, further be coated with a sustained release matrix, Applicant's composition as recited in the specification and claim 15 includes acarbose that is combined with the sustained release matrix, whether or not there is a further coating on the composition. It is the combination, not merely coating, of acarbose and a sustained release matrix through which Applicant achieves a true sustained release of the composition. Applicant is not claiming merely an acarbose composition with a sustained release coating, but rather the combined mixture of acarbose with a sustained release matrix. Therefore, Applicant's invention is patentably distinct over the disclosure of the '663 reference.

Thus, because the Patel et al. reference fails to disclose each and every element of the claims as filed, the reference cannot support the §102(e) rejection and should be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102(e)

The Examiner has rejected claims 28-41 as being anticipated by the '874 reference. The Examiner states that the '874 reference discloses glucosidase and/or amylase inhibitors that can be manufactured as pharmaceutical compositions for the combined use with a lipase inhibitor in the treatment of obesity (Office action, p.4).

The '874 reference specifically recites that glucosidase and/or amylase inhibitors, used in monotherapy in combination with a reduction diet bring about "practically no weight loss" (see Column 4, 2nd paragraph). Furthermore, the '874 reference states that it is the *combined use* of glucosidase and/or amylase inhibitors *in combination with a lipase inhibitor* that results in weight loss (emphasis added).

Applicant's claim 28 is not anticipated by the '874 reference. Applicant's Claim 28 claims a method for treating a patient to stimulate weight loss comprising an acarbose formulation. Contrary to the '874 reference, Applicant claims that the composition of acarbose combined with a sustained release matrix, in and of itself, will result in the stimulation of weight loss in a subject, i.e., the '874 reference does not teach the use of an acarbose, and likewise, the combination of acarbose and sustained release matrix composition, for the stimulation of weight loss. The '874 clearly teaches against Applicant's composition of using acarbose (a glucosidase and/or amylase inhibitor), alone, to treat obesity and therefore, the '874 does not teach Applicant's invention. Accordingly, Applicant's invention is not anticipated by the '874 reference.

The Examiner has rejected claims 15-27 as being anticipated by the '874 reference. Applicant submits that the '874 reference does not teach the use of an acarbose and sustained release matrix composition for the stimulation of weight loss. Again, the '874 reference specifically recites that glucosidase and/or amylase inhibitors used in monotherapy do not result in weight loss. Furthermore, the '874 reference states that it is only the combined use of glucosidase and/or amylase inhibitors in combination with a lipase inhibitor that results in weight loss.

However, Applicant's amended Claim 15 claims a composition including acarbose and a sustained release matrix that is used to stimulate weight loss of a patient. Applicant's disclosure suggests that the composition of acarbose combined with a sustained release matrix, in and of itself, will result in the stimulation of weight loss in a subject. The '874 reference expressly teaches that the *combination of* acarbose with a lipase inhibitor is suitable for treatment of obesity. As such, the '874 clearly teaches against Applicant's composition claims to treat obesity, the '874 does not teach Applicant's invention, and the '874 reference does not anticipate Applicant's invention.

REJECTIONS UNDER 35 U.S.C. § 103(a)

The Examiner initially states that the application names joint inventors. However, this is incorrect. The subject application names a sole inventor, James U. Morrison. Therefore,

Applicant respectfully submits that it is not necessary to point out the inventor and invention dates for each claim not commonly owned at that time a later invention was made.

The Examiner has rejected claims 28-42 as being unpatentable over the '854 reference in view of the '663 reference. Applicant respectfully submits that one of the requirements to establish a *prima facie* case of obviousness is that the combined prior art references must teach or suggest each and every limitation in the subject claim. Neither the '854 reference nor the '663 reference provide any suggestion or motivation to actually combine a cellulose ether-based coating in combination with ethyl cellulose with a glucosidase and/or amylase inhibitor to treat obesity. Absent such suggestion or motivation, it is improper to combine the references in support of an obviousness rejection under 35 U.S.C. § 103. Only through Applicant's teaching is one motivated to combine a cellulose ether-based coating in combination with ethyl cellulose with a glucosidase and/or amylase inhibitor to treat obesity. The Examiner has not provided any motivation to combine these two elements in the claimed method of stimulating weight loss.

Furthermore, Applicant's Claim 28 claims a method for treating a patient to stimulate weight loss comprising an acarbose formulation. The Examiner states that the '874 reference discloses that glucosidase and/or amylase inhibitors can be combined with lipase inhibitors to treat obesity. However, Applicant's invention does not utilize lipase inhibitors in combination with acarbose to stimulate weight loss. The '874 reference specifically states that, used alone, glucosidase and/or amylase inhibitors, such as acarbose, do not result in weight loss. This is a teaching clearly contrary to the teaching in the instant application and claims. As such, the '854 reference does not teach applicant's invention as disclosed in claims 28-41.

Moreover, the Examiner states that the '663 reference discloses a cellulose ether-based coating in combination with ethyl cellulose, and that such coating may be used to coat a hydrophilic therapeutic agent such as acarbose. However, the '663 reference gives no indication that acarbose that is coated with such cellulose ether-based coating may be used for the treatment of obesity. Therefore, there is no motivation to combine the '663 reference with the '874 reference. Accordingly, the rejection should be withdrawn and the present case should be passed to issue.

Applicant also asserts that newly added claim 43 further claims subject matter patentable over the references of record and are thus in condition for allowance. Applicant respectfully requests an early indication thereof.

Respectfully submitted,

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By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

(Amended) 1. A method for producing an extended-release composition comprising mixing acarbose with a sustained release matrix **[to create said composition], such that said acarbose and sustained release matrix are combined to form a mixture**.

(Amended) 15. A chemical composition **used to stimulate weight loss in a patient,**
comprising:
acarbose; and
a sustained release matrix**,**
wherein said acarbose and sustained release matrix are combined to form a mixture.

(New) 43. **A method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.**